DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

1015 5 MAY 13 P2:33

MAY 10 2005

Mr. Alexander P. Hughes
President
MD Drinks, Inc.
901 Tenth Street
Suite 206
Santa Monica, California 90403

Dear Mr. Hughes:

This is in response to your letter of April 27, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that MD Drinks, Inc. is making the following claim, among others, for the product **FUNCTION URBAN DETOX:**

> "[B]everage that helps cure and prevent hangovers...."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate diseases, such as the consequences of alcohol poisoning/overdose (i.e., hangover). This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

You also describe your product as a "beverage." 21 U.S.C. 321(ff) defines the term "dietary supplement." As defined by the Act, dietary supplements do not include products represented for use as conventional foods. 21 U.S.C. 321(ff)(2)(B). The product described above, in that it is being described as a "beverage," is being represented as analogous to, or an alternative to, similar products that are conventional foods. In doing so, this product is being represented for use as a conventional food. Therefore, in that it is represented for use as conventional food, it is not a dietary supplement within the meaning of 21 U.S.C. 321(ff) and claims made for it are not subject to 21 U.S.C. 343(r)(6).

Instead, this product appears to be a conventional food that must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, it must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the product in its labeling if they are claims defined by 21 U.S.C. 343(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. If you intend to market this product as a conventional food and you have any questions about the status of any of its ingredients, you should direct them to FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740.

Please contact us if we may be of further assistance.

Sincerely yours,

Robert J Moore

for Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

CTS 9153 30 day

MD Drinks, Inc.
901 Tenth Street
Suite 206
Santa Monica, California 90403

MAY - 5 2005

April 27, 2005

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

~~To whom it may concern:~~

This letter is to notify you that MD Drinks, Inc. (the "Company") will be marketing, distributing and selling a product whose label bears a statement made under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act. Pursuant to 21 CFR 101.93(a)(2), please find the following information below: (i) name and address of the Company, (ii) the text of the statement the Company is making, (iii) the names of the dietary ingredients or supplements that are the subject of the statement and (iv) the name of the dietary supplement (including its brand name) on whose label the statement appears.

1. Name and address of the Company:

   MD Drinks, Inc.
   901 Tenth Street, Suite 206
   Santa Monica, California 90403

2. Text of the statement the Company is making:

   "FUNCTION is a physician-developed beverage that helps cure and prevent hangovers, helps protect your liver, helps reduce the effect of urban pollution on your lungs and sinuses, and boosts your immune system."

3. The names of the dietary ingredients or supplements that are the subject of the statement:

   a. Opuntia Ficus Indica
   b. N-acetyl cysteine
   c. Calcium carbonate
   d. Sodium
   e. Ascorbic acid (Vitamin C)
   f. Magnesium oxide

g. Riboflavin
h. Vitamin B6
i. Vitamin B12
j. Folic acid

4. The name of the dietary supplement (including its brand name) on whose label the statement appears:

Function Urban Detox

Thank you very much, and please do not hesitate to contact me at the above address if you have any additional questions.

Sincerely yours,

Alexander P. Hughes
President, MD Drinks, Inc.

MD Drinks, Inc.
901 Tenth Street
Suite 206
Santa Monica, California 90403

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